

CHARTER
FOR THE
U.S. ARMY MEDICAL RESEARCH
AND MATERIEL COMMAND
MEDICAL RESEARCH INFORMATION TECHNOLOGY SYSTEM
(MeRITS)
FUNCTIONAL
INTEGRATED PRODUCT TEAM
18 JULY 2002

Charter for the U.S. Army Medical Research and Materiel Command (USAMRMC) Medical Research Information Technology System (MeRITS) Functional Integrated Product Team (IPT)

1. PURPOSE. This charter establishes and outlines the membership and responsibilities of the functional Integrated Product Team (IPT) for the Medical Research Information Technology System (MeRITS).

2. RESPONSIBILITIES. The functional IPT will assist the program manager in designing and implementing the MeRITS Project. The MeRITS will provide for a Command-wide system that will acquire, analyze, store, manage, and publish electronic data and documents for collaboration with our commercial co-development partners, and for submission to the Food and Drug Administration (FDA). Functional IPT responsibilities include:

- a. Identify the current business processes ("as-is") and existing, relevant information systems and databases, define the new processes ("to-be") based on FDA regulations and Guidances, and identify the gaps in these two states,
- b. Develop the MeRITS functional requirements document, and the changes needed to close the gaps,
- c. Develop the functional evaluation criteria to be used in evaluating alternative solutions for the MeRITS,
- d. Identify, evaluate and prioritize candidate solutions that meet the requirements,
- e. Provide recommendations on major decision issues to the CG, USAMRMC, who will serve as the milestone decision authority for acquisition of the MeRITS,
- f. Ensure that the MeRITS will comply with the FDA Title 21 Code of Federal Regulations Part 11, other relevant regulations, FDA Guidances, and DOD specific or unique requirements,
- g. Provide implementation guidance for the MeRITS at the user level.

3. MEMBERSHIP.

a. Chairperson. The MeRITS Project Manager, Headquarters, USAMRMC will serve as Chairperson of the IPT. The Deputy Project Manager will serve as the alternate Chair in the absence of the Chair. The Chair will endeavor to reach a full consensus on all issues, but, as needed, he/she will call for a vote to assist him/her in arriving at a decision. Both dissenting and majority opinions on major decision issues will be submitted to the decision authority. The Chair will be accountable to the Commanding General, USAMRMC. The Chair may recommend to the CG the addition or removal of members from the IPT as needed.

b. Core Members.

- Each core member represents a major user group of the MeRITS,
- has one vote,
- must actively participate in achieving the goals of the MeRITS,
- is expected to have the authority for the organization they represent,
- will accept appropriate taskings relevant to their functional areas.

The principals or their designees from the following organizations will constitute the core membership of the MeRITS functional IPT:

- (1) U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Medical Division

- (2) USAMRIID, Office of Product Development and Regulatory Affairs
- (3) Walter Reed Army Institute of Research (WRAIR), Division of Communicable Diseases and Immunology
- (4) WRAIR, Division of Retrovirology
- (5) WRAIR, Division of Experimental Therapeutics
- (6) WRAIR, Associate Director, OCONUS Laboratories
- (7) WRAIR, Office of Research Management
- (8) U.S. Army Medical Materiel Development Activity (USAMMDA), Quality Assurance Office and Pharmaceuticals System Division
- (9) Headquarters, USAMRMC, Office of Regulatory Compliance and Quality

c. Advisory Members. Advisory members will participate in the IPT meetings and provide input to the voting process.

- (1) Headquarters, USAMRMC, Deputy Commander
- (2) Headquarters, USAMRMC, Medical Acquisition Program Manager
- (3) Headquarters, USAMRMC, Animal Care and Use Review Office, Regulatory Compliance and Quality
- (4) Headquarters, USAMRMC, Congressionally Directed Medical Research Program (CDMRP)
- (5) Headquarters, USAMRMC, Staff Judge Advocate
- (6) Headquarters, USAMRMC, Deputy for Information Management and Information Technology
- (7) Headquarters, USAMRMC, Deputy for Resource Management
- (8) U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- (9) U.S. Army Research Institute of Environmental Medicine (USARIEM)
- (10) U.S. Army Aeromedical Research Laboratory (USAARL)
- (11) U.S. Army Institute of Surgical Research (USAISR)
- (12) WRAIR, Division of Biometrics
- (13) USAMRIID, Office of Applications Development, Biometrics and Information Management Department
- (14) U.S. Army Medical Information Management Center (USAMIMC).
- (15) U.S. Army Medical Research Acquisition Activity (USAMRAA)

d. Ad hoc Members. At the discretion of the Chair, the MeRITS IPT membership can be expanded to include ad hoc representatives from other technology or specialty activities or offices.

4. MEETINGS.

a. The MeRITS IPT Chair will establish the agenda for scheduled meetings. Any member of the MeRITS IPT may submit proposed agenda items to the MeRITS PMO for inclusion at the next available meeting. The Chair will be respectful of members' time and, although all members are invited to attend meetings, the agenda will make it clear which members (both core and advisory) will be needed to address the agenda items for each meeting. Minutes will be prepared for each meeting. A summary of action items, action agencies, and suspense dates will be prepared before the end of a meeting. Draft minutes of each meeting will be prepared and distributed to all core members for staffing prior to final release. All action items from previous meetings will be reviewed to determine that the action is closed or adequate progress is being made toward resolution.

b. Use of Electronic Media. Electronic meetings will be utilized when convenient and appropriate. Instructions and procedures for conducting electronic meetings will be prepared and distributed by the MeRITS PMO. As appropriate and at the discretion of the MeRITS IPT Chair, the review and coordination of any documents will be accomplished by utilizing network or web-based resources.

5. TERM. The terms of this Charter are in effect upon the date of the signature of the approval authority. They will be reviewed annually and amended as required. No organization will terminate their participation in the MeRITS IPT without first notifying the IPT Chair in writing at least 30 days in advance and concurrence by the approval authority.

6. REFERENCES.

- a. Food and Drug Administration (FDA) 21 Code of Federal Regulations Part 11, March 1997
- b. FDA Guidance for Industry, Computerized Systems Used Clinical Trials, April 1999
- c. FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format – General Considerations, January 1999
- d. FDA Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA) / Establishment License Application (ELA) and New Drug Application (NDA)] - 11/12/1999, REVISED 11/22/1999
- e. FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - NDAs - January 1999
- f. Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format - Investigational New Drug Applications (INDs) - 26 March 2002
- g. DoD Directive 5000.1, The Defense Acquisition System, (Incorporating Change 1, January 4, 2001), 23 October 2000
- h. DoD Regulation 5000.2-R, Mandatory Procedures for Major Defense Acquisition Programs (MDAPS) and Major Automated Information System (MAIS) Acquisition Programs, 5 April 2002

APPROVAL:



Lester Martinez-Lopez
Major General, MC
Commanding General



Date

Suggested MeRITS IPT Core/Advisory Members

| Organization | Function | Suggested Member | Suggested Alternate |
|-----------------|---|------------------|-------------------------------|
| Core | | | |
| HQ, USAMRMC | Chair | COL Brueckner | David Dasso |
| | RCQ | Brenda Meredith | Mary Burman |
| USAMRIID | OPDRA | Ed Brown | Judy Pace |
| | Medical Division/SIP | LTC Kortepeter | Dr. Boudreau |
| WRAIR | ORM | Sara Rothman | TBD |
| | Retrovirology | COL McNeil | Phil Renzullo, Merlin Robb |
| | CD&I | LTC Kester | LTC Magill |
| | ET | TBD | TBD |
| | OCONUS Labs | COL Hartman | TBD |
| USAMRICD | | TBD | TBD |
| USAMMDA | Advanced Development Product Management & QA | MAJ Altman | Scott Doughty |
| Advisory | | | |
| HQ, USAMRMC | Senior Leadership | COL Davies | TBD |
| | Medical Acquisition Program Manager | Bill Howell | MAJ Bernritter |
| | Deputy for Resource Management | TBD | TBD |
| | RCQ – Animal Care and Use Review Office | TBD | TBD |
| | CDMRP | TBD | TBD |
| | Dep. for Information Management and Information Technology | LTC Murray | Phylis Rinehart |
| | Staff Judge Advocate | TBD | TBD |
| USAMIMC | IT | Mike Jewett | Tim Cannon |
| USAMRAA | Contracting | Cheryl Miles | TBD |
| USAMRIID | Office of Applications Development, Biometrics and Information Management Dept. | TBD | TBD |
| WRAIR | Biometrics Division | LTC Weishaar | TBD |

ACTION SUMMARY SHEET

For use of this form, see OTSG Reg 21-51; the proponent agency is the OTSG

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SUBJECT Establishment of the Medical Research and Information Technology Systems (MeRITS) Functional Integrated Product Team (IPT)**SUSPENSE DATE****DATE**

18 Jul 02

SUMMARY OF ACTION : (Briefly describe purpose, discussion/background and recommendation for the action.)

Purpose: To obtain decisions on approval of the charter for the Medical Research and Information Technology Systems (MeRITS) functional Integrated Product Team (IPT), appointment of a Chairperson, and identification of core and advisory members of the IPT.

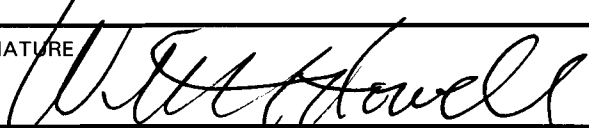
Discussion/Background: Establishment of the functional IPT will allow users of the new research system that is being developed to make recommendations to MG Martinez-Lopez, who serves as the milestone decision authority for development and acquisition of the new Command-wide MeRITS. It is recommended that COL Ralf Brueckner be appointed as the Chairperson of this IPT. A memorandum from the Commanding General to Commanders and Directors is needed to ensure their support in appointing IPT core and advisory members who will participate fully in all IPT activities.

A draft of the IPT charter has been circulated to RCQ, USAMMDA, USAMRICD, WRAIR, USAARL, USAISR, USARIEM and USAMRIID. Comments and suggested changes have been received and used in finalizing the charter. All concur in the creation and charter of the functional IPT.

Recommendation: That MG Martinez-Lopez approve the MeRITS Functional IPT Charter, with COL Ralf Brueckner as the Chairperson.

Tab - A MeRITS Functional IPT Charter

Tab - B Suggested MeRITS IPT Core/Advisory Members

| COORDINATIONS (Continue on reverse if necessary) | | | | REVIEWS/APPROVALS | | | |
|--|-------------------|-------|-----------|-------------------|------|------|------|
| OFFICE | NAME | INITI | DATE | | NAME | INIT | DATE |
| MCMR-SGS | MAJ Blount | MB | 19 Jul 02 | BR CH | | | |
| MCMR-ZX | COL Raulin | R | 23 Jul 02 | DIV CH | | | |
| MCMR-ZB | COL Davies | D | 23 Jul 02 | DIR/OFC CH | | | |
| MCMR-ZA | MG Martinez-Lopez | M | 27 Jul 02 | ASST EXEC | | | |
| | | | | EXEC | | | |
| | | | | DSG | | | |
| | | | | TSG | | | |
| | | | | SACO | | | |
| TYPE NAME AND GRADE OF ACTION OFFICER/PHONE NUMBER /OFFICE SYMBOL William H. Howell / 301.619.3272 / MCMR-ZF | | | | DISPATCHED | | | |
| | | | | SACO COMMENTS: | | | |
| SIGNATURE  | | | | | | | |